



DEPARTMENT OF HEALTH AND HUMAN SERVICE

912621
Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
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October 11, 2001

WARNING LETTER NO. 2002-NOL-02

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Chi Thangh Nguyen, Owner
Carmel's Seafood
5268 Lakeshore Road
Bay St. Louis, Mississippi 39520-9547

Dear Mr. Nguyen:

On September 10-13, 2001, a U.S. Food and Drug Administration (FDA) investigator and microbiologist conducted an inspection of your crabmeat processing and oyster repacking facility, located at 5268 Lakeshore Road, Bay St. Louis, Mississippi. The inspection was conducted to determine compliance with FDA's seafood processing regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123) and the Current Good Manufacturing Practice (CGMP) requirements for foods, 21 CFR 110. The inspection did not cover your oyster repacking operation. Our investigator and microbiologist documented numerous deviations, some of which were previously brought to your attention, that cause your product to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (Act). They are adulterated because they have been prepared, packed or held under conditions whereby they may become contaminated with filth. You can find this Act and the seafood HACCP regulations through Internet links in FDA's homepage at www.fda.gov.

During the inspection, the investigator and microbiologist collected samples of your cooked, ready-to-eat claw crabmeat and lump crabmeat. The samples were subsequently analyzed for the presence of microorganisms. You should be aware that *Listeria monocytogenes* was recovered from one sample, collected on September 11, 2001, of the cooked, ready-to-eat claw crabmeat. You already may have received a letter from our Southeast Regional Laboratory in Atlanta, Georgia, notifying you of the same. The presence of *Listeria monocytogenes* causes your crabmeat to be in violation of Section 402(a)(3) of the Act.

Listeria monocytogenes is a pathogenic microorganism, which can cause the serious foodborne bacterial illness known as "listeriosis." Listeriosis can be a serious illness for some people; especially the elderly, newborns, pregnant women and those with weakened immune systems. This bacteria is widely present

in the environment: food processors and handlers should take all precautions necessary to reduce the risk of contamination and to keep food safe from *Listeria monocytogenes*. Since *Listeria monocytogenes* is a tough microorganism to control, you may want to consider referring to the expertise of a consultant to control and eliminate this pathogen from your processing facility and products. We strongly recommend you determine the cause(s) of this problem and take corrective action as soon as possible.

The deviations from FDA's seafood HACCP regulations were as follows:

You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the condition and cleanliness of food contact surfaces with sufficient frequency to ensure control as evidenced by:

- Tables used in the picking operation had crabmeat residues from previous operations;
- Plastic tubs used to store picked crabmeat had residues from previous batches; and,
- Aprons worn by employees were encrusted with crabmeat residues from previous operations.

During the inspection, our investigator documented numerous insanitary conditions. The inspection found that you have not taken effective measures to exclude pests from the processing areas and to protect against the contamination of food. For example:

- Numerous flies were observed in the cooking/backing room and in both of the picking/packing rooms;
- Numerous flies were observed on cooked crabs during the backing operation;
- Flies were observed in the receiving area, the back dock area, and on the side of the plant; and,
- Two cats were observed in the back dock area and toilet facility.

Employees working in direct contact with food and food contact surfaces did not take necessary precautions to protect against contamination of those items from microorganisms or foreign substances. For example:

- Employees did not sanitize their gloves or hands after handling unsanitized objects and then handling cooked crabs;
- Employees placed perforated containers, filled with cooked, backed crabs and crab claws, directly on the wet floor; and,
- A utensil with a dirty cloth wrapped around the handle was used to pick crab claw meat.

In addition, our investigator documented unsanitary conditions associated with the construction and design of your facility. For example:

- Plastic curtains leading into the processing facility were left open allowing flies to enter the processing areas; and,
- Trash and rotting debris, from previous operations and located adjacent to the plant, provides a potential reservoir for pathogens and attracts flies.

Given this, we expect you to notify this office in writing, within 15 days from your receipt of this letter, outlining specific actions you have taken to correct the deficiencies and to assure that such violations will not recur. Include copies of any available documentation demonstrating that corrections have been made. If you cannot complete all corrections before you respond, we expect you will explain the reason for the delay and a deadline by which you will correct any remaining deficiencies.

This letter does not list all the deviations at your facility. A copy of the FDA 483 that was discussed with you on September 13, 2001 is enclosed. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations, and CGMP's for foods. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations. Failure to implement corrective action may result in regulatory action initiated by FDA without further notice. This action may include product seizure and/or injunction against you and your company.

Send your reply to Rebecca A. Asente, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Ms. Asente at (504) 253-4519.

Sincerely,



Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483